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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,775	07/14/2008	**Yoko Yamaguchi**	062819	7966

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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
11/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,775	YAMAGUCHI ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/07, 9/21/06, 7/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Giordano et al. (Investigative Ophtalmology & Visual Science, August 1995, Vol. 34, No. 9)

Giordano et al .teaches that the addition of a biodegradable polymer to trans-retinoic acid for sustained delivery (abstract). The addition of the polymer to trans-retinoic acid results in a suspension (page 2744, column 2). The Materials and Methods section (page 2744, column 1) teaches that all-trans vitamin A acid was used in the polymer.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (Application of hard retinoic acid nanoparticles for skin regeneration, March 2002; translation attached.)

Yamaguchi et al. disclose that an in vivo study of blood kinetics found that the nanoparticles behave as highly effective drug delivery system formulation. The particles were hydrodynamically characterized as spherical particles with a diameter of approximately 125 to 164 nm (page 2, first paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giordano et al. (Investigative Ophtalmology & Visual Science, August 1995, Vol. 34, No. 9) in view of Yamaguchi et al. (Application of hard retinoic acid nanoparticles for skin regeneration, March 2002; translation attached.)

Giordano et al .teaches that the addition of a biodegradable polymer to trans-retinoic acid for sustained delivery (abstract). The addition of the polymer to trans-retinoic acid results in a suspension (page 2744, column 2). The Materials and Methods section (page 2744, column 1) teaches that all-trans vitamin A acid was used in the polymer.

Giordano et al. is silent on use of nanoparticles.

Yamaguchi et al. disclose that an in vivo study of blood kinetics found that the nanoparticles behave as highly effective drug delivery system formulation of all trans retinoic acid. The particles were hydrodynamically characterized as spherical particles with a diameter of approximately 125 to 164 nm (page 2, first paragraph).

One of ordinary skill in the art would have found it prima facie obvious to administer trans-retinoic acid in a nanoparticle size which ranged from 5 to 300 nm. One would have been motivated to do so because it is known in the art that nanoparticles allow for an effective drug delivery system and further a biodegradable polymer is known for the same use, per Giordano et al. Therefore, given that (i) nanoparticles in the range of 5 to 300 nm and (ii) biodegradable polymers are known to enhance the delivery of trans-retinoic acid, one would have been motivated to combine the two in order to achieve enhanced delivery of trans-retinoic acid.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giordano et al. (Investigative Ophtalmology & Visual Science, August 1995, Vol. 34, No. 9) in view of Yamaguchi et al. (Application of hard retinoic acid nanoparticles for skin regeneration, March 2002; translation attached.) as applied to claims 1-4 and 6-8 above, and further in view of Remington's Pharmaceutical Sciences (pages 420-425, 1980).

The combination of Giordano et al. (Investigative Ophtalmology & Visual Science, August 1995, Vol. 34, No. 9) in view of Yamaguchi et al. (Application of hard retinoic acid nanoparticles for skin regeneration, March 2002; translation attached.)) is set forth supra. The combination differs by not claiming salt forms.

The use of pharmaceutically acceptable salts of the elected compound would have been a matter well within the purview of the skilled artisan. As taught by Remington's Pharmaceutical Sciences, drugs may be formulated into salts to modify the duration of action of a drug; to modify the transportation and distribution of a drug in the body; to reduce toxicity; and to overcome difficulties encountered in pharmaceutical formulation procedures or in the dosage form itself (see column 2 of page 424, first paragraph). Thus, it would have been prima facie obvious to the skilled artisan motivated by any one or more of these factors to formulate the active agent into a pharmaceutically acceptable salt to enhance the pharmacokinetic parameters of the drug or to reduce the toxicity with the reasonable expectation that the therapeutic benefit of the agent in salt form would have been the same or substantially similar to that of the agent itself.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1613

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614